

### **REMARKS**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 29, 2004. Claims 1-279 remain pending, and claims 246-279 are withdrawn from consideration. Claims 1, 49, 62, 110, 123, 170, 171, 173, 178-180, 182, and 184 have been amended and claims 16, 106, 109, and 167-169 have been canceled. Support for the amendments can be found in the substitute specification (clean copy version), originally filed claims and replacement drawings at, for example, page 37, line 19 through page 33, line 10; page 105 lines 5-13; and FIGS. 38A and 38B. No new matter has been added. Reconsideration and reexamination are respectfully requested.

#### **Information Disclosure Statement**

Applicants bring to the Examiner's attention that an Information Disclosure Statement was filed on November 12, 2003, but have not received an initialed Form PTO-1449 indicating consideration by the Examiner. A copy of the OIPE date-stamped postcard, the Information Disclosure Statement, Form PTO-1449, and the foreign and technical art are enclosed. Applicants request that the Examiner consider the IDS and return an initialed Form PTO-1449 with the next PTO communication.

#### **Objections to the Specification**

Pursuant to 37 CFR § 1.125(a)-(c), a substitute specification is included herewith, including updating the co-pending data and amending figure numbers. Numerous grammatical errors have also been corrected. No new matter has been added to the substitute specification.

#### **Objections to the Claims**

The dependencies of claims 49, 110, and 171 have been corrected. The Examiner's assumptions regarding the proper dependencies are correct.

#### **Rejection under 35 U.S.C. § 112**

Claims 49, 110, 171, and 232 are rejected as being indefinite. The claims have been amended to correct the dependencies. Withdrawal of the rejection is requested.

**Rejection under 35 U.S.C. § 102(b)**

Claims 1, 4, 5, 8, 9, 11, 12, 14, 21, 22, 40-42, 45-47, 56, 57, 62, 65, 66, 69, 70, 72, 73, 75, 82, 83, 95, 101-103, 106-108, 117, 118, 123, 126, 127, 130, 131, 133, 134, 136, 143, 144, 156-158, 162-164, 167-169, 178, and 179 are rejected as being anticipated by Moe (US 3,566,860). Applicants traverse the rejection.

Independent claim 1 has been amended to include the limitations of original claim 16, which was indicated as allowable. Moe does not teach or suggest a lead electrode assembly including an electrode, riser, and head in which the proximal end of the riser is closer to the distal end at the top of the riser than at the bottom of the riser, as is recited in independent claim 1 and the claims dependent thereon.

Independent claim 62 has been amended to include the limitations of original claim 109, which was indicated as allowable. Moe does not teach or suggest a lead electrode assembly including an electrode, a foundation, a backing layer between the electrode and foundation, a riser, and a head, as is recited in claim 62 and the claims dependent thereon.

Independent claim 123 has been amended to recite an electrode assembly including an electrode, a foundation coupled to the electrode, a riser coupled to the foundation, and a head coupled to the riser. Claim 123 also recites that a bottom surface of the head is coupled to a top surface of the riser, a bottom surface of the riser is coupled to a top surface of the foundation, and a bottom surface of the foundation is coupled to a top surface of the electrode. This is not taught or suggested in Moe. The electrode assembly of Moe includes a crown 16, neck 14, and outwardly extending portion (no reference number), with an adhesive patch 18 and peeloff protective layers 28, 26. Even if one considers the crown, neck and outwardly extending portion of the electrode as the head, riser, and electrode of the instant invention, Moe fails to teach a foundation having a top surface coupled to the riser and a bottom surface coupled to a top surface of the electrode, as is recited in claim 123. If the adhesive patch 18 is considered the foundation, the bottom of the riser (neck 14) is not coupled to the top surface of the patch. As shown in FIGS. 1 and 4 of Moe, adhesive patch 18 surrounds neck 14, but does not extend underneath neck 14. Alternatively, if one considers the protective layers 28, 26 as the foundation, then the riser (neck 14) is not coupled to the foundation. Thus, there is no interpretation of Moe that anticipates each and every limitation of independent claim 123 and the

claims dependent thereon. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-3, 6, 7, 11, 12, 14, 19-22, 40-42, 45, 46, 63, 64, 67, 68, 72, 73, 75, 80-83, 106, 123-125, 128, and 129 are rejected as being anticipated by Corasanti (US 3,841,312). Applicants traverse the rejection.

Independent claim 1 has been amended to include the limitations of original claim 16, which was indicated as allowable. Corasanti fails to teach or suggest a lead electrode assembly including an electrode, riser, and head in which the proximal end of the riser is closer to the distal end at the top of the riser than at the bottom of the riser, as is recited in independent claim 1 and the claims dependent thereon.

Independent claim 62 has been amended to include the limitations of original claim 109, which was indicated as allowable. Corasanti fails to teach or suggest a lead electrode assembly including an electrode, a foundation, a backing layer between the electrode and foundation, a riser, and a head, as is recited in claim 62 and the claims dependent thereon.

Independent claim 123 has been amended to recite an electrode assembly including an electrode, a foundation coupled to the electrode, a riser coupled to the foundation, and a head coupled to the riser. The electrode assembly of Corasanti includes an electrode having a door knob shaped portion 40 positioned over an extension member 38 and flange 36 (see Corasanti FIGS. 3, 8, 9). Corasanti also teaches gel pads 46, 50 and adhesive pad 48. However, neither the gel pads, adhesive pad, nor any other element of the Corasanti electrode assembly can be equated with the foundation of the instant claims, which has a top surface coupled to the bottom surface of the riser and a bottom surface coupled to a top surface of the electrode. In the electrode assembly of Corasanti, the "riser" or extension member 38 is coupled directly to the remaining body of the electrode. Corasanti thus fails to teach each and every limitation of the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2, 6, 10-14, 19, 21, 22, 24-28, 34, 40-42, 45-47, 56-58, 62, 63, 67, 71-75, 80, 82, 83, 85-89, 95, 101-103, 106-108, 117-119, 123, 124, 128, 132-136, 139, 141, 143, 144, 146-

150, 156, 162-164, 167-169, and 178-180 are rejected as being anticipated by Lemole (US 4,553,554). Applicants traverse the rejection.

Independent claim 1 has been amended to include the limitations of original claim 16, which was indicated as allowable. Lemole fails to teach or suggest a lead electrode assembly including an electrode, riser, and head in which the proximal end of the riser is closer to the distal end at the top of the riser than at the bottom of the riser, as is recited in independent claim 1 and the claims dependent thereon.

Independent claim 62 has been amended to include the limitations of original claim 109, which was indicated as allowable. Lemole fails to teach or suggest a lead electrode assembly including an electrode, a foundation, a backing layer between the electrode and foundation, a riser, and a head, as is recited in claim 62 and the claims dependent thereon.

Independent claim 123 has been amended to recite an electrode assembly including an electrode, a foundation coupled to the electrode, a riser coupled to the foundation, and a head coupled to the riser. The electrode assembly of Lemole includes a ventricular contact 20 coupled to a nonconductive carrier 14 and also coupled to signal wires 16a, 16b. Even if one were to interpret the various parts of the ventricular contact 20 of Lemole as an electrode, riser and head, Lemole does not teach or suggest a foundation coupled to the electrode such that a bottom surface of the riser is coupled to a top surface of the foundation, and a bottom surface of the foundation coupled to a top surface of the electrode, as is recited in claim 123. Lemole thus fails to teach each and every limitation of the claims. Reconsideration and withdrawal of the rejection is respectfully requested.

### **Rejection under 35 U.S.C. § 103**

Claims 15, 17, 18, 23-39, 51-55, 60, 61, 76, 78, 79, 84-94, 96-100, 104, 105, 112-116, 121, 122, 137, 139-142, 145-155, 159-161, 173-177, 182-184, 187, 188, 191, 192, 198, 200, 201-225, 228-230, and 234-244 are rejected as being unpatentable over Moe. As stated above, Moe fails to teach the limitations of the independent claims 1, 62, and 123, and the claims dependent therefrom. Additionally, Moe does not provide any motivation for modifying his electrode assembly to achieve the instant invention. The electrode assembly of Moe is designed with a single, unitary electrode, with a portion forming the male part of a snap connector. There is no

motivation for one to modify this design to add additional foundation or backing layers, or to modify the actual electrode to have a head and riser portion separated from the body of the electrode, as in the instant claims. The electrode of Moe is specifically designed to be readily secured to the skin of a patient, and to connect to the female snap conductors applied to leads of electrical monitoring equipment (see Moe, column 1, lines 71-75 and column 2, lines 48-50). There is no motivation for one of ordinary skill in the art to modify the external electrode of Moe for subcutaneous implantation. The entire disclosure of Moe is directed to providing a simple external electrode to be removably attached to a patient's skin.

Regarding independent claim 184, and the claims dependent thereon, as Moe is directed to providing an external electrode to be connected to an external circuitry, there is no motivation for one to add a biocompatible housing sized and configured for subcutaneous implantation. Moe neither teaches nor suggests the limitations of the claims. Withdrawal of the rejection is respectfully requested.

Claims 59, 81, 120, 181, 184-186, 189, 190, 193-197, 202-205, 207-211, 217, 223-225, 228-230, and 239-242 are rejected as being unpatentable over Lemole. For at least the reasons set forth above, Lemole fails to teach the limitations of independent claims 1, 62, and 123. Additionally, Lemole does not provide any guidance or suggestion for modifying his electrode assembly to achieve the instant invention. There is no motivation for one to add further elements such as the claimed foundation or backing layer.

Regarding independent claim 184 and the claims dependent thereon, the Examiner asserts that it would have been obvious to add a housing to protect the pacing circuitry of Lemole. Lemole, however, teaches the electrode assembly as being attached to an external pacemaker (see column 2, line 39). Claim 184, as amended, recites a biocompatible housing sized and configured for subcutaneous implantation in a patient. As Lemole specifically teach using an external pacemaker, there is no motivation to add and/or modify any housing to be biocompatible and sized and configured for subcutaneous implantation. Withdrawal of the rejection is respectfully requested.

Reexamination and reconsideration are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Gust H. Bardy et al.

By their Attorney,

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Attachment: Copy of OIPE Date-Stamped Postcard  
Copy of November 12, 2003 IDS  
Copy of November 12, 2203 Form PTO-1449  
45 Cited Non-U.S. Patent/Publication References  
38 Replacement Drawing Sheets